ATTACHMENT I - copy of a certified translation of United States provisional patent application serial number 60/253,749 filed November 29, 2000

STI

CERTIFICATION

Schreiber Translations, Inc.

51 Monroe Street

Suite 101

Rockville, MD 20850

P: 301.424.7737

F: 301.424.2336

This is to certify that the attached English language document, identified as Device for Use in Micro-Invasive Surgical Procedures, and Guide Catheter and Valve Unit for a Device for Use in Micro-Invasive Surgical Procedures, is a true and accurate translation of the original German language document to the best of our knowledge and belief.

Executed this 6th day
of December, 2000

Margaret J. Flynn
Senior Editor
Schreiber Translations, Inc.
51 Monroe Street, Suite 101
Rockville, Maryland 20850

translation@schreibernet.com

www.schreibernet.com

Device for Use in Micro-Invasive Surgical Procedures, and Guide Catheter and Valve Unit for a Device for Use in Micro-Invasive Surgical Procedures

The invention relates to a device for use in micro-invasive surgical procedures, comprising a valve unit and a guide catheter that can be connected to the valve unit, into which a guide wire and an instrument catheter, which is fitted with an instrument and can be slid along the guide wire, can be inserted through the valve unit.

The invention further relates to a guide catheter for a device for use in micro-invasive surgical procedures, into which a guide wire and an instrument catheter, which is fitted with an instrument and can be slid along the guide wire, can be inserted through a valve unit in the device.

The invention further relates to a valve unit for a device for use in micro-invasive surgical procedures, which can be connected to a guide catheter, into which a guide wire and an instrument catheter, which is fitted with an instrument and can be slid along the guide wire, can be inserted through the valve unit.

A device of this type, a guide catheter of this type, and a valve unit of this type are known in the art, for example, from DE 198 23 064 C2. The state-of-the-art device is equipped with a valve unit that can be connected to a guide catheter, in which process a dilation catheter as the instrument catheter is inserted through the valve unit into the guide catheter along a guide wire. The dilation catheter is equipped with an expandable balloon as its instrument, which, after being pushed out through the distal end of the guide catheter, can be used to treat vasoconstrictions via dilation. However, the known device, the known guide catheter, and the known valve unit that is used with a known device or a known guide catheter have the disadvantage that in order to permit a sufficient quantity of contrast medium for vasography to pass through, the guide outer diameter of

the catheter must be relatively large, which results in a relatively high degree of trauma at the point of entry into a blood vessel.

The object of the invention is to provide a device, a guide catheter, and a valve unit of the type described at the beginning that will make it possible to introduce a sufficient quantity of contrast medium into the vascular region to be handled or treated in diagnostic or therapeutic micro-invasive surgical procedures, while the outer diameter of the guide catheter is kept relatively small.

This object is attained in accordance with the invention with a device, a guide catheter, and a valve unit of the type described at the beginning, in that a hydraulic bypass section is provided, wherein, when a section of the enclosure of the guide catheter is close-fitting for the instrument, and the cross-section of the guide catheter corresponds basically to the largest cross-section of the instrument itself, the bypass section has a larger hydraulic cross-section than the guide catheter cross-section, and a length that corresponds to at least the length of the largest cross-section of the instrument.

Since the invention provides for a bypass section having a hydraulic cross-section that is larger than the guide cross-section of the instrument catheter, at least in the area of the instrument, which may be a dilatable balloon or some other diagnostic or therapeutic instrument, a part of which is larger in its cross-section than a guide shaft of the instrument catheter, while the length of this hydraulic cross-section corresponds at least to the length of the largest cross-section of the instrument, it is now possible to introduce a quantity of contrast medium sufficient for imaging procedures into the vessel that is to be handled or treated, after the instrument has been retracted into the bypass section, even in cases in which the guide catheter lies very close to the instrument, without requiring that the instrument catheter be removed from the valve unit or retracted into the valve unit. This makes treatment through micro-invasive surgery substantially easier.

A further improvement on the device specified in the invention advantageously provides for the bypass section to be an integral part of the guide catheter.

In accordance with one embodiment of the above-mentioned further improvement on the device specified in the invention, it is advantageously provided that the bypass section is positioned in the area of the proximal end of the guide catheter.

In accordance with another embodiment of the above-named embodiment of the device specified in the invention, the bypass section is positioned advantageously between the proximal end and the distal end of the guide catheter.

In one implementation of the above-named embodiment of the device specified in the invention, the bypass section is advantageously designed to have a flexible, expandable wall.

In a further improvement on the latter implementation of the device specified in the invention, the bypass section is further advantageously designed to have an expandable reinforcement structure.

In a further implementation of the above-named embodiment of the device specified in the invention, the bypass section is advantageously designed to have a bypass sheath that encloses the guide catheter, is sealed at its edges, and is attached to the wall of the guide catheter; and to have recesses that are built into the wall of the guide catheter near the edges of the bypass sheath.

In a further implementation of the above-named embodiment of the device specified in the invention, the bypass section is advantageously designed to

have a number of grooves that extend through the wall of the guide catheter, wherein the grooves are sealed with an outer sheath.

In one embodiment of the latter implementation of the device specified in the invention, which is equipped with the aforementioned grooves, the grooves are oriented lengthwise along the guide catheter.

In another embodiment of the latter implementation of the device specified in the invention, which is equipped with the aforementioned grooves, the grooves are designed to be coiled in a spiral.

In the further improvement on the device specified in the invention having a bypass section that is integrated into the guide catheter, and is positioned between the proximal end and the distal end of the guide catheter, and in the related implementations, it is advantageously provided that edge markers are included along the edges of the bypass section for use in imaging procedures.

In another further improvement on the device specified in the invention, it is advantageously provided that the bypass section is designed to form a single unit together with the valve unit, as a distal end section.

In another further improvement on the device specified in the invention, it is advantageously provided that the bypass section is designed as a torsion-proof, flexible or rigid intermediate segment that can be inserted between the guide catheter and the valve unit.

In the latter further improvement on the device specified in the invention, one embodiment advantageously provides that the intermediate segment can be connected without torsion to the guide catheter.

In the latter two further improvements, and in related improvements on the device specified in the invention, the length of the bypass section and the length of the valve unit through which the instrument catheter is inserted, together advantageously correspond to at least the length of a section that slides along the guide wire between the distal end of the instrument and a point of exit for the guide wire on the guide shaft.

In a further improvement on the guide catheter specified in the invention it is advantageously provided that the bypass section is positioned in the area of the proximal end of the guide catheter.

In another further improvement on the guide catheter specified in the invention, it is advantageously provided that the bypass section is positioned between the proximal end and the distal end of the guide catheter.

In one implementation of the latter further improvement on the guide catheter specified in the invention, the bypass section is advantageously designed to have a flexible, expandable wall.

In one embodiment of the latter implementation of the guide catheter specified in the invention, the bypass section is designed to have an expandable reinforcement structure.

In a further implementation of the latter further improvement on the guide catheter specified in the invention, the bypass section is designed to have a bypass sheath that encloses the guide catheter and is connected to the wall of the guide catheter and sealed at the edges; and to have recesses built into the wall of the guide catheter in the area of the edges of the bypass sheath.

In a further implementation of the latter further improvement on the guide catheter specified in the invention, it is advantageously provided that at least the

bypass section is designed to have a number of grooves that extend through the wall of the guide catheter, wherein the grooves are sealed by an outer sheath.

In one embodiment of a guide catheter having grooves, as specified in the invention, the grooves are oriented lengthwise along the guide catheter.

In a further embodiment of a guide catheter having grooves, as specified in the invention, the grooves are coiled in a spiral.

In the further improvement on the guide catheter specified in the invention that has a bypass section that is positioned between the proximal end and the distal end of the guide catheter, edge markers are advantageously provided along the edges of the bypass section for use in imaging procedures.

In one embodiment of the valve unit specified in the invention, it is provided that the bypass section is designed to form a single unit with the valve unit, as a distal end section.

In another embodiment of the valve unit specified in the invention it is provided that the bypass section is designed as an intermediate segment that is connected to the valve unit such that it can be removed.

In one further improvement on the latter embodiment of the valve unit specified in the invention, the intermediate segment can be advantageously connected to a guide catheter such that the segment cannot rotate.

Further advantageous embodiments and advantages of the invention are the object of the following description of exemplary embodiments, with reference to the figures in the diagrams. These show:

Fig. 1 a partial side view cross-section of a first exemplary

embodiment of the invention having a bypass section that is positioned at the proximal end of a guide catheter;

Fig. 2 a partial side view cross-section of a second exemplary embodiment of the invention, having a bypass section that is designed to form a single unit with a valve unit;

Fig. 3 a partial side view cross-section of a third exemplary embodiment of the invention, having a bypass section that is designed as a separate intermediate segment;

Fig. 4 a partial side view cross-section of a fourth exemplary embodiment of the invention, having a bypass section that is positioned in the distal end area of a guide catheter, and is equipped with a reinforcement structure;

Fig. 5 the exemplary embodiment as illustrated in Fig. 4, having a dilated balloon, positioned in the bypass section, as its instrument;

Fig. 6 the bypass section of the exemplary embodiment as illustrated in Fig. 4 and Fig. 5, in which the reinforcement structure is enlarged following dilation of the balloon;

Fig. 7 a partial side view cross-section of a fifth exemplary embodiment of the invention, having a bypass section that is positioned in the distal end area of a guide catheter, and is equipped with a bypass sheath;

Fig. 8 a partial side view cross-section of a section of a sixth exemplary embodiment of the invention, having a bypass

section that is designed to have a number of grooves built into the wall of the guide catheter;

Fig. 9 a section of the guide catheter in the exemplary embodiment as illustrated in Fig. 8, in the area of the bypass section, having an outer sheath, shown here as partially open, which encloses the grooves;

Fig. 10 a section of a guide catheter in a modification on the exemplary embodiment as illustrated in Fig. 8 and Fig. 9, in the area of the bypass section, having an outer sheath, shown here as partially open, which encloses the grooves;

Fig. 11 a cross-section of the exemplary embodiment as illustrated in Fig. 8, equipped with a reinforcement structure that is attached to the bridges that are formed between the grooves.

Fig. 1 shows a first exemplary embodiment of the invention in a partial cross-section of a side view. The device as illustrated in Fig. 1 is equipped with a valve unit 1, which in the first exemplary embodiment is a state-of-the-art, so-called Y-valve. The valve unit 1 can be connected via a rotating coupling 2 to a proximal end 3 of a guide catheter 4 in the device. In the area of the proximal end 3 of the guide catheter 4, a bypass section 5, which has an enlarged hydraulic cross-section, is positioned as the proximal end section 6 of the guide catheter 4. The guide catheter 4 can be inserted through a tissue wall 7 using an insertion valve 8, wherein, when the device is used as intended, a section 9 that is positioned inside the body has an inner diameter that is smaller than the inner diameter at the proximal end section 6 of the guide catheter 4. The device as illustrated in Fig. 1 is equipped with an expandable balloon 10 as the instrument, which is connected via known means to an instrument catheter that is designed as a dilation catheter 11. The inner diameter of the inner-corporal section 9

corresponds generally to the outer diameter of the balloon 10, which is equipped with a guide wire 12 and a guide shaft 13 that is positioned at the proximal end of the balloon 10, wherein a certain length of the guide wire 12 extends inside the guide shaft 13, emerging from the guide shaft 13 at a point of exit 14.

In accordance with the requirements of the known, micro-invasive surgical technique of vasodilation in which an expandable balloon 10 is used, the valve unit 1, the coupling 2, and the insertion valve 8 are arranged such that when the corresponding insertion points have been sealed, the guide wire 12 can be pushed beyond the distal end 15 of the guide catheter 4, into the vascular region to be dilated. After the guide wire 12 has been positioned, the balloon 10 can be introduced into the guide catheter 4 through the valve unit 1 by advancing the guide shaft 13 along the guide wire 12, and can be advanced along the inner-corporal section 9 up to the vascular region that is to be dilated.

After dilation has been completed by expanding the balloon 10, the balloon 10 can be retracted into the bypass section 5, wherein the bypass section 5 and the section of the valve unit 1 that takes up the guide wire 12 and the guide shaft 13 together have a length that is greater than the distance between the distal end 16 of the balloon 10 and the point of exit 14. Now, a contrast medium can be introduced into the valve unit 1 via known methods, flowing past the balloon 10, through the inner-corporal section 9 of the guide catheter 4, and into the vascular area that is to be dilated, without requiring that the dilation catheter 11, part of which lies between the point of exit 14 and the distal end 16 of the balloon 10, be removed from the valve unit 1 or retracted into the valve unit 1. Thus, after the success of the dilation has been evaluated, the balloon 10 can again be easily advanced through the inner-corporal section 9 of the guide catheter 4 into the vascular area that is to be dilated, to allow further dilation if required.

Fig. 2 shows a partial side view cross-section of a second exemplary embodiment of a device as specified in the invention, wherein elements that

correspond to those in the first exemplary embodiment as illustrated in Fig. 1 and in the second exemplary embodiment as illustrated in Fig. 2 are assigned the same reference numbers, and are not discussed further here. In the second exemplary embodiment as illustrated in Fig. 2, the bypass section 5 is designed to form a single unit with the valve unit 1, as the rigid, distal end section 17 of the valve unit, having an inner diameter that is greater than the inner diameter of the inner-corporal section 9, which corresponds to the outer diameter of the uninflated balloon 10, wherein the coupling 2 is now positioned at the distal end of the distal end section 17. The length of the distal end section 17 and the section of the valve unit 1 that lies in the extension of the distal end section 17, is such that the dilation catheter 11, with its section that lies between the distal end 16 of the balloon 10 and the point of exit 14, lies within the distal end section 17 and the valve unit 1. Hence, use of this embodiment is basically the same as with the first exemplary embodiment as illustrated in Fig. 1.

Fig. 3 shows a partial side view cross-section of a third exemplary embodiment of a device as specified in the invention, wherein corresponding elements from the first exemplary embodiment as illustrated in Fig. 1, from the second exemplary embodiment as illustrated in Fig. 2, and from the third exemplary embodiment as illustrated in Fig. 3 are assigned the same reference numbers, and are not described further. In the third exemplary embodiment in accordance with Fig. 3, the bypass section 5 is designed as a separate intermediate segment 18 that in this exemplary embodiment is torsion-free, and can be connected to the proximal coupling 2 of the valve unit 1, as well as to the proximal end 3 of the guide catheter, via an intermediate coupling 19. As with the preceding exemplary embodiments, the intermediate segment 18 has an inner diameter that is greater than the inner diameter of the inner-corporal section 9 of the guide catheter 4, which corresponds to the outer diameter of the undilated balloon 10. In addition, the length of the intermediate segment 18 is such that the section that lies between the distal end 16 of the balloon 10 and the point of exit 14 can

be positioned entirely within the intermediate segment 18 and the section of the valve unit 1 that lies within the extension.

In the third exemplary embodiment as illustrated in Fig. 3, the intermediate coupling 19 preferably forms a rotating connection between the guide catheter 4 and the intermediate segment 18, wherein the guide catheter 4 can be rotated around a swivel nut that is rigidly attached to the catheter. Use of the third exemplary embodiment is basically the same as with the first exemplary embodiment as illustrated in Fig. 1 and the second exemplary embodiment as illustrated in Fig. 2.

In the exemplary embodiments described in reference to Fig. 1 through Fig. 3 it is advantageous for the bypass section 5 to be transparent, either entirely or in slit-shaped sections, in order to enable the visual monitoring of the positioning of the balloon 10.

Fig. 4 shows a partial side view cross-section of a fourth exemplary embodiment of a device as specified in the invention, wherein elements that correspond to elements from the preceding exemplary embodiments are assigned the same reference numbers, and are not discussed further. The device illustrated in Fig. 4 is equipped with a guide catheter 4 at the distal end 15 of which a bypass section 5 is provided, which has an expandable reinforcement structure 20, also referred to as a stent. The reinforcement structure 20 is incorporated into the wall of the guide catheter 4, wherein the wall of the guide catheter 4 in the area of the reinforcement structure 20 is designed to be flexible and deformable relative to the other areas. The length of the reinforcement structure 20 is greater than the length of the balloon 10. Thus it is advantageous to design the reinforcement structure 20 to have a limited expansion, with the maximum diameter of the bypass section 5 preferably corresponding to the outer diameter of the insertion valve 8.

At the edge of the bypass section 5, edge markers 21 are built into the wall of the guide catheter 4, which clearly mark the ends of the bypass section 5 for use in imaging procedures.

Fig. 5 shows a partial side view cross-section of the fourth exemplary embodiment as illustrated in Fig. 4, having a dilation catheter 11 that has been inserted through the valve unit 1 into the guide catheter 4. In the arrangement illustrated in Fig. 5, the balloon 10 lies inside the reinforcement structure 20 in the bypass section 5, which is not shown in Fig. 5 for purposes of improving clarity of the diagram. In this positioning, the balloon 10 is expanded via known methods, at various positions, so that the guide catheter 4 expands in the area of the bypass section 5 over a length that is greater than the length of the balloon 10.

Fig. 6 shows a partial side view cross-section of the fourth exemplary embodiment as illustrated in Fig. 4 and Fig. 5, after the balloon 10 has been expanded in the position illustrated in Fig. 5. As can be seen from Fig. 6, the reinforcement structure 20 is now expanded in its cross-section, and the wall of the guide catheter 4 has also been expanded. Now, an undilated balloon 10 can be positioned inside the bypass section 5, wherein a quantity of contrast medium that is sufficient to allow imaging of the vessel that is to be dilated or has already been dilated is allowed to flow through the stabilized expansion of the reinforcement structure 20, and the wall of the guide catheter 4 into the bypass section 5.

Following completion of the micro-invasive surgical procedures, the guide catheter 4 can be retracted, wherein the guide catheter 4 is removed together with the insertion valve 8, or the outer diameter of the bypass section 5 is first reduced to its original size, and then is guided through the fixed insertion valve 8; the guide catheter 4 is then drawn out through the insertion valve 8 prior to the removal of the insertion valve 8.

Fig. 7 shows a partial side view cross-section of a fifth exemplary embodiment of a device as specified in the invention, wherein elements of the fifth exemplary embodiment that correspond to elements that are described in the first exemplary embodiment through the fourth exemplary embodiment are assigned the same reference numbers, and are not discussed further. In the fifth exemplary embodiment as illustrated in Fig. 7, a bypass section 5 is provided, and is positioned in the area of the distal end 15 of a guide catheter 4. The bypass section 5 in accordance with the fifth exemplary embodiment is equipped with a bypass sheath that at least partially encloses the outer wall of the guide catheter 4, and is attached to the wall of the guide catheter 4 at the proximal end and the distal end of the bypass section 5, and is sealed at the edges.

In one embodiment, the bypass sheath 22 is made of a flexible, expandable material. In another embodiment, the bypass sheath 22 is folded, wherein the bypass sheath 22 unfolds when a certain level of pressure has been reached inside the guide catheter.

In the area of the distal end and the proximal end of the bypass section 5, a number of recesses 23 are built into the wall of the guide catheter 4, and are designed to connect the inner lumina of the guide catheter 4 with a bypass volume that develops between the wall of the guide catheter 4 and the bypass sheath 22. In this, the recesses 23 that are built into the distal end of the bypass section 5 are separated from the recesses 23 built into the proximal end of the bypass section 5 by a distance that corresponds at least to the length of the balloon 10.

In the fifth exemplary embodiment as illustrated in Fig. 7, the balloon 10 can be retracted into the bypass section 5 following dilation of the vessel, allowing a sufficient quantity of a contrast medium that has been introduced through the valve unit 1 into the inner lumina of the guide catheter 4 to flow through the

bypass volume and out of the distal end 15 of the guide catheter 4, into the vessel that is to be treated.

Also in the fifth exemplary embodiment as illustrated in Fig. 7, it is advantageous to provide edge markers 21 that will clearly indicate the end areas of the bypass section 5 to aid in imaging procedures.

Fig. 8 shows a partial side view cross-section of a sixth exemplary embodiment of a device as specified in the invention, illustrating a section of the distal end of a guide catheter, wherein elements that correspond to elements discussed in connection with the preceding exemplary embodiments are assigned the same reference numbers, and will not be discussed further. In the sixth exemplary embodiment as illustrated in Fig. 8, the bypass section 5 is designed to be positioned in the area of the distal end 15 of the guide catheter 4, and is equipped with grooves 24 that are built into the wall of the guide catheter 4, and extending through the wall of the guide catheter 4; these grooves preferably extend around the entire circumference of the wall of the guide catheter 4, and are oriented lengthwise along the guide catheter 4. The length of the grooves corresponds at least to the length of the balloon 10. The grooves 24 are enclosed on the outside by a thin outer sheath 25, which seals the edges of the bypass section 5.

Fig. 9 shows a section of the guide catheter 4 from the exemplary embodiment as illustrated in Fig. 8, in the area of the bypass section 5, with an outer sheath 25, shown here partially open. As can be seen in Fig. 9, bridges 26 are present between the grooves, which support the outer sheath 25 and guarantee adequate rigidity against torsion for the guide catheter 4.

The outer sheath 25 is preferably also connected to the outside surfaces of the bridges 26 that are built up between the grooves 24, and is made to be flexible or folded, thus further increasing the hydraulic cross-section.

Fig. 10 shows a section of a guide catheter 4 in the area of the bypass section 5, in a modification on the exemplary embodiment as illustrated in Fig. 8, having an outer sheath 25 that is shown here partially open. In the embodiment illustrated in Fig. 10, the grooves 24, and thus also the bridges 26, are designed as spiral coils. This embodiment offers the advantage of reducing the risk that a balloon 10 could remain in the grooves 24 following dilation thus seriously impeding the flow of contrast medium.

Fig. 11 shows a cross-section of the bypass section 5 from the exemplary embodiment as illustrated in Fig. 8 and in Fig. 9, or the related modification as illustrated in Fig. 10. As can be seen in Fig. 11, a reinforcement structure 27 is integrated into the bridges 26, being formed, for example, from wire, mesh netting, or rigid plastic inserts; this reinforcement structure serves to ensure a high level of resistance to torsion for the bypass section 5.

During a positioning of the balloon 10 in the bypass section 5 in accordance with Fig. 8 or Fig. 10, the hydraulic cross-section is now expanded via the grooves 24 in order to allow a sufficient quantity of contrast medium to flow through. Hence, a sufficient quantity of contrast medium can flow past even an inner wall of the guide catheter 4 that is lying close to an unexpanded balloon 10, in order to allow imaging of the vessel that is to be handled or treated.

PATENT CLAIMS

1. Device for use in micro-invasive surgical procedures, comprising a valve unit and a guide catheter that is connected to the valve unit, wherein a guide wire and an instrument catheter that is fitted with an instrument can be inserted through the valve unit and advanced along the guide wire in the guide catheter, **characterized in that** a hydraulic bypass section (5) is provided, wherein, when a section of the enclosure of the guide catheter (4) is close-fitting for the instrument (1), and the cross-section of the guide catheter corresponds basically to the largest cross-section of the instrument itself (1), the bypass section has a larger hydraulic cross-section than the guide catheter cross-section, and a length that corresponds to at least to the length of the largest cross-section of the instrument (10).

2. Device in accordance with Claim 1, characterized in that the bypass section (5) is integrated into the guide catheter (4).

3. Device in accordance with Claim 2, characterized in that the bypass section (5) is positioned in the area of the proximal end (3) of the guide catheter (4).

4. Device in accordance with Claim 2, characterized in that the bypass section (5) is positioned between the proximal end (3) and the distal end (15) of the guide catheter (4).

5. Device in accordance with Claim 4, characterized in that the bypass section (5) is designed to have a flexible, expandable wall.

6. Device in accordance with Claim 5, characterized in that the bypass section (5) is designed to have an expandable reinforcement structure (20).

7. Device in accordance with Claim 4, characterized in that the bypass section (5) is designed to have a bypass sheath (22) that encloses the guide catheter (4) and is connected to the wall of the guide catheter (4), being sealed at its edges; and to have recesses (23) that are built into the wall of the guide catheter (4), near the edges of the bypass sheath (22).

8. Device in accordance with Claim 4, characterized in that at least the bypass section (5) is designed to have a number of groves (24) that extend through the wall of the guide catheter (4), wherein the grooves (24) are sealed by an outer sheath (25).

9. Device in accordance with Claim 8, characterized in that the grooves (24) are oriented lengthwise along the guide catheter (4).

10. Device in accordance with Claim 8, characterized in that the grooves (24) are designed to be coiled in a spiral.

11. Device in accordance with one of Claims 4 through 10, characterized in that edge markers (21) are provided along the edges of the bypass section (5) for use in imaging procedures.

12. Device in accordance with Claim 1, characterized in that the bypass section (5) is designed to form a single piece with the valve unit (1), as a distal end section (6).

13. Device in accordance with Claim 1, characterized in that the bypass section (5) is designed as an intermediate segment (18) that can be inserted between the guide catheter (4) and the valve unit (1).

14. Device in accordance with Claim 13, characterized in that the intermediate segment (18) can be connected torsion-free to the guide catheter (4).

15. Device in accordance with one of Claims 3, 12, 13, or 14, characterized in that the bypass section (5) is either entirely transparent, or transparent in at least one slit-shaped partial section.

16. Device in accordance with one of Claims 12 through 15, characterized in that the length of the bypass section (5) and the length of the valve unit (1), into which the instrument catheter (11) is inserted, together correspond to at least the length of a section between the distal end (16) of the instrument (10) that slides along the guide wire, and a point of exit (14) for the guide wire (12) out of the guide shaft (13).

17. Guide catheter for a device for use in micro-invasive surgical procedures, into which a guide wire and an instrument catheter that is fitted with an instrument and can be slid along the guide wire can be inserted through a valve unit in the device, **characterized in that** a hydraulic bypass section (5) is provided, wherein, when a section of the enclosure of the guide catheter (4) is close-fitting for the instrument (1) and the cross-section of the guide catheter corresponds basically to the largest cross-section of the instrument itself (1), the bypass section has a larger hydraulic cross-section than the guide catheter cross-section, and a length that corresponds to at least the length of the largest cross-section of the instrument (10).

18. Guide catheter in accordance with Claim 17, characterized in that the bypass section (5) is positioned in the area of the proximal end (3) of the guide catheter (4).

19. Guide catheter in accordance with Claim 17, characterized in that the bypass section (5) is positioned between the proximal end (3) and the distal end (15) of the guide catheter (4).

20. Guide catheter in accordance with Claim 19, characterized in that the bypass section (5) is designed to have a flexible, expandable wall.

21. Guide catheter in accordance with Claim 20, characterized in that the bypass section (5) is designed to have an expandable reinforcement structure (20).

22. Guide catheter in accordance with Claim 19, characterized in that the bypass section (5) is designed to have a bypass sheath (22) that encloses the guide catheter (4) and is connected to the wall of the guide catheter (4), with its edges being sealed, and to have recesses (23) built into the wall of the guide catheter (4) near the edges of the bypass sheath (22).

23. Guide catheter in accordance with Claim 19, characterized in that at least the bypass section (5) is designed to have a number of grooves (24) that extend through the wall of the guide catheter (4), wherein the grooves (24) are sealed by an outer sheath (25).

24. Guide catheter in accordance with Claim 23, characterized in that the grooves (24) are oriented lengthwise along the guide catheter (4).

25. Guide catheter in accordance with Claim 23, characterized in that the grooves (24) are designed to be coiled in a spiral.

26. Guide catheter in accordance with one of Claims 19 through 25, characterized in that edge markers (21) are provided along the edges of the bypass section (5) for use in imaging procedures.

27. Valve unit for a device for use in micro-invasive surgical procedures that can be connected to a guide catheter, into which an instrument catheter, which is fitted with an instrument and can be slid along the guide wire, can be inserted through the valve unit, **characterized in that** a hydraulic bypass section (5) is

provided, wherein, when a section of the enclosure of the guide catheter (4) is close-fitting for the instrument (1), and the cross-section of the guide catheter corresponds basically to the largest cross-section of the instrument itself (1), the bypass section has a larger hydraulic cross-section than the guide catheter cross-section, and a length that corresponds to at least the length of the largest cross-section of the instrument (10).

28. Valve unit in accordance with Claim 27, characterized in that the bypass section (5) is designed to form a single unit with the valve unit (1), as a distal end section (6).

29. Valve unit in accordance with Claim 27, characterized in that the bypass section (5) is designed as an intermediate segment (18) that is connected to the valve unit (1) such that it can be removed.

30. Valve unit in accordance with Claim 29, characterized in that the intermediate segment (18) can be connected to a guide catheter (4) such that it is torsion-free.

ABSTRACT

Device for Use in Micro-Invasive Surgical Procedures and
Guide Catheter and Valve Unit
for a Device for Use in Micro-Invasive Surgical Procedures

In a device for use in micro-invasive surgical procedures, and a guide catheter and a valve unit for a device for use in micro-invasive surgical procedures, a bypass section (5) having an enlarged hydraulic cross-section is provided, into which an instrument (10), for example a balloon, on an instrument catheter (11) can be retracted after treatment has been administered, thus allowing a sufficient quantity of contrast medium to flow past the instrument (1) and out of the guide catheter (4). By providing the bypass section (5) with an enlarged cross-section, it becomes possible to use instruments (10) with very close-fitting guide catheters (4).

Fig. 1